



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0795, EPA-HQ-OPP-2015-0796

and EPA-HQ-OPP-2015-0797; FRL-9957-22]

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the ovicide/miticide hexythiazox in or on beet, sugar, root, and beet, sugar, dried pulp and establishes tolerances associated with regional registrations for residues on Bermuda grass, forage and Bermuda grass, hay. This regulation also modifies the existing tolerances associated with regional registrations in or on alfalfa, forage; and alfalfa, hay. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). The regulation also removes the existing time-limited tolerance for residues on beet, sugar, root because it is superseded by the new beet, sugar, root tolerance and removes the tolerance for residues “Fruit, citrus group 10” of 0.35 ppm because it is superseded by the existing tolerance for “Fruit, citrus group 10-10” of 0.6 ppm.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The dockets for this action, identified by docket identification (ID) numbers EPA-HQ-OPP-2015-0795, EPA-HQ-OPP-2015-0796 and EPA-HQ-OPP-2015-0797, are available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, P.E., Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfrNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID numbers EPA-HQ-OPP-2015-0795, EPA-HQ-OPP-2015-0796 and EPA-HQ-OPP-2015-0797 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID numbers EPA-HQ-OPP-2015-0795, EPA-HQ-OPP-2015-0796 and EPA-HQ-OPP-2015-0797, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 16, 2016 (81 FR 14030) (FRL-9942-86), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of three (3) pesticide petitions (PP 5F8396, 5F8412 & 5F8413) by Gowan Company, P.O. Box 5569, Yuma, AZ 85366-5569. These petitions requested that 40 CFR 180.448 be amended by (1) establishing tolerances for residues of the hexythiazox in or on Bermuda grass, forage at 40 parts per million (ppm) (PP 5F8412); Bermuda grass, hay at 70 ppm (PP 5F8412); beet, sugar, dried pulp at 0.60 ppm (PP 5F8413); beet, sugar, molasses at 0.21 ppm (PP 5F8413); beet, sugar, roots at 0.15 ppm (PP 5F8413); and beet, sugar, tops at 1.5 ppm (PP5F8413); and (2) modifying the existing tolerances for residues in or on alfalfa, forage from 15 ppm to 20 ppm (PP 5F8396) and alfalfa, hay from 30 ppm to 60 ppm (PP 5F8396). These documents referenced a summary of the petitions prepared by Gowan Company, the registrant, which are available in the docket, <http://www.regulations.gov>. Several comments were received in response to the notice of filing, objecting generally to the presence of pesticide residues in food. Because none of the comments provided any information for the Agency to consider in its review of the requested

hexythiazox tolerances and because the Agency has concluded based on available data that the tolerances requested meet the FFDCA safety standard, EPA is not granting the commenters' requests to deny the petition.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for hexythiazox including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with hexythiazox follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also

considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Hexythiazox has low acute toxicity by the oral, dermal, and inhalation routes of exposure. It produces mild eye irritation and is not a skin irritant or skin sensitizer. Hexythiazox is associated with toxicity of the liver and adrenals following subchronic and chronic exposure to dogs, rats, and mice, with the dog being the most sensitive species. The prenatal developmental studies in rabbits and rats and the 2-generation reproduction study in rats showed no indication of increased susceptibility to *in utero* or postnatal exposure to hexythiazox. Reproductive toxicity was not observed. There is no concern for immunotoxicity or neurotoxicity following exposure to hexythiazox. The toxicology database for hexythiazox does not show any evidence of treatment-related effects on the immune system.

Hexythiazox is classified as “Likely to be Carcinogenic to Humans” based on a treatment-related increase in benign and malignant liver tumors in female mice and the presence of mammary gland tumors (fibroadenomas) in male rats; however, the evidence as a whole was not strong enough to warrant the use of a linear low dose extrapolation model applied to the animal data (Q_1^*) for a quantitative estimation of human risk because the common liver tumors (benign and malignant) were only observed in high-dose female mice, and benign mammary gland tumors were only observed in high-dose male rats. Since the effects seen in the study that serves as the basis for the chronic reference dose (cRfD) occurred at doses substantially below the lowest dose that induced tumors (and there is no mutagenic concern for hexythiazox), the cRfD is considered protective of all chronic effects, including potential carcinogenicity.

Specific information on the studies received and the nature of the adverse effects caused by hexythiazox as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at

<http://www.regulations.gov> within the document entitled “Hexythiazox. Human Health Risk Assessment for Section 3 Registration on Bermuda Grass and Amended Registrations for Use on Beet, sugars, Alfalfa, and Potatoes,” which can be found in docket ID numbers EPA-HQ-OPP-2015-0795, EPA-HQ-OPP-2015-0796 and EPA-HQ-OPP-2015-0797.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment.

PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>. A summary of the toxicological endpoints for hexythiazox used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Hexythiazox for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects

Acute Dietary (All populations)	No risk is expected from this exposure scenario as no hazard was identified in any toxicity study for this duration of exposure		
Chronic Dietary (All populations)	NOAEL= 2.5 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.025 mg/kg/day cPAD = 0.025	One-Year Feeding Toxicity Study - Dogs LOAEL = 12.5 mg/kg/day based on increased absolute and relative adrenal weights, and associated adrenal histopathology.
Incidental Oral Short-Term (1 to 30 days) and Intermediate-Term (1 to 6 months)	NOAEL= 30 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	2-Generation Reproduction Study – Rat LOAEL = 180 mg/kg/day, based on decreased pup body weight during lactation and delayed hair growth and/or eye opening, and decreased parental body-weight gain and increased absolute and relative liver, kidney, and adrenal weights.
Dermal Short- and Intermediate-term	A quantitative dermal risk assessment is not necessary since no dermal hazard is anticipated. There is no evidence of increased quantitative or qualitative susceptibility of the young following <i>in utero</i> and pre-and post-natal exposure to hexythiazox.		
Inhalation Short-Term (1 to 30 days) and Intermediate-Term (1 to 6 months)	Oral NOAEL= 30 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	2-Generation Reproduction Study – Rat LOAEL = 180 mg/kg/day, based on decreased pup body weight during lactation and delayed hair growth and/or eye opening, and decreased parental body-weight gain and increased absolute and relative liver, kidney, and adrenal weights.
Cancer (oral, dermal, and inhalation)	Classification: “Likely to be Carcinogenic to Humans.” A quantification of risk using a non-linear approach; <i>i.e.</i> , RfD, for hexythiazox will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to hexythiazox.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to hexythiazox, EPA considered exposure under the petitioned-for tolerances as well as all existing hexythiazox tolerances in 40 CFR 180.448. EPA assessed dietary exposures from hexythiazox in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for hexythiazox; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary (food and drinking water) exposure assessment, EPA used the Dietary Exposure Evaluation Model (DEEM-FCID), Version 3.16, which uses food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) from 2003- 2008. As to residue levels in food, EPA used tolerance-level residues, assumed 100 percent crop treated (PCT), and incorporated DEEM 7.81 default processing factors when processing data were not available.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to hexythiazox. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *Chronic exposure*.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for hexythiazox. Tolerance-level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for hexythiazox in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of hexythiazox. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Because surface water and groundwater estimated drinking water concentrations (EDWCs) from the proposed new uses on Bermuda grass and sugar beets (ranging from 1.29 to 2.78 µg/L) do not produce EDWCs greater than those produced from a recent drinking water assessment (D429192, 9/21/2015) (ranging from 3.5 to 7.3 µg/L) using the Mississippi soybeans scenario, the Agency is relying on the EDWCs from that previous drinking water assessment. Based on that assessment, the EDWCs of hexythiazox for chronic exposures are estimated to be 4.3 ppb for surface water and 2.4 ppb for ground water. The higher of these numbers was directly entered into the dietary exposure model for the chronic dietary risk assessment.

3. *From non-dietary exposure*. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Hexythiazox is currently

registered for the following residential uses, including ornamental landscape plantings, turf, and fruit and nut trees in residential sites.

EPA assessed residential exposure using the following assumptions: Residential handler exposures are expected to be short-term (1 to 30 days) via either the dermal or inhalation routes of exposures. Since a quantitative dermal risk assessment is not needed for hexythiazox, handler MOEs were calculated for the inhalation route of exposure only. Both adults and children may be exposed to hexythiazox residues from contact with treated lawns or treated residential plants. Post application exposures are expected to be short-term (1 to 30 days) and intermediate-term (1 to 6 months) in duration. Adult post-application exposures were not assessed since no quantitative dermal risk assessment is needed for hexythiazox and inhalation exposures are typically negligible in outdoor settings. The exposure assessment for children included incidental oral exposure resulting from transfer of residues from the hands or objects to the mouth, and from incidental ingestion of soil.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/science/residential-exposure-sop.html>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found hexythiazox to share a common mechanism of toxicity with any other substances, and hexythiazox does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action; therefore, EPA has assumed that

hexythiazox does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children.

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology data base indicates no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to hexythiazox.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for hexythiazox is complete.
- ii. There is no indication that hexythiazox is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that hexythiazox results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to hexythiazox in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by hexythiazox.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected; therefore, hexythiazox is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to hexythiazox from food and water will utilize 93% of the cPAD for children 1 to 2 years of age, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of hexythiazox is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Hexythiazox is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to hexythiazox. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, drinking water, and residential inhalation exposures result in an aggregate MOE for adults (7,700) that greatly exceeds the LOC of 100, and is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Hexythiazox is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to hexythiazox. Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded the combined intermediate-term food, drinking water, and residential oral exposures result in an aggregate MOE for children (1,150) that greatly exceeds the LOC of 100, and is not of concern.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III. C.1.iii., EPA concluded that regulation based on the cRfD will be protective for both chronic and carcinogenic risks. As noted in this unit, there are no chronic risks of concern.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. general population, or to infants and children from aggregate exposure to hexythiazox residues.

IV. Other Considerations

A. Analytical Enforcement Methodology.

An adequate analytical enforcement methodology, high performance liquid chromatography method with UV detection (HPLC/UV), is available to enforce the tolerance expression for hexythiazox and its metabolites containing the PT-1-3 moiety in crop and livestock commodities. This method is listed in the U.S. EPA Index of Residue Analytical Methods under hexythiazox as method AMR-985-87.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for hexythiazox for alfalfa, forage and hay; and beet, sugar roots and top.

C. Revisions to Petitioned-for Tolerances

The petitioner requested tolerances for beet, sugar, molasses and beet, sugar, dried pulp based on the raw agricultural commodity (RAC) tolerance level instead of the HAFT (Highest Average Field Trial). Using the HAFT to determine the tolerance for these processed commodities, EPA determined that residues in the molasses would be covered by the tolerance on the beet, sugar, root; therefore, a separate molasses tolerance is not required. Using the HAFT for beet, sugar, dried pulp, EPA determined that the tolerance should be reduced to 0.30 ppm. Beet, sugar, tops are no longer considered a major livestock food commodity for regulatory purposes; therefore, a tolerance is not required for beet, sugar, tops.

V. Conclusion

Therefore, tolerances are established for residues of the ovicide/miticide hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety in or on beet, sugar, root at 0.15 ppm and beet, sugar, dried pulp at 0.30 ppm. Tolerances associated with regional registrations are established for Bermuda grass, forage (EPA Regions 9-10 only) at 40 parts per million (ppm) and Bermuda grass, hay (EPA Regions 9-10 only) at 70 ppm. Also, existing tolerances are modified for residues in or on Alfalfa, forage (EPA Regions 7-11 only) at 20 ppm and Alfalfa, hay (EPA Regions 7-11 only) at 60 ppm.

Because the new tolerance for beet, sugar, root (in 40 CFR 180.448(a)) supersedes the existing time-limited tolerance for beet, sugar, root (in 40 CFR 180.448(b)), the Agency is removing the time-limited tolerance.

In addition, in the previous rulemaking establishing hexythiazox tolerances, EPA instructed the **Federal Register** staff to revise the existing entry in the table in paragraph (c) for “Fruit, citrus group 10 (CA, AZ, TX only)” at 0.35 ppm to “Fruit, citrus group 10-10 (CA, AZ, TX only)” at 0.6 ppm. (April 6, 2016, 81 FR 19891). Instead of revising the existing entry, a separate entry was created for “Fruit, citrus group 10-10 (CA, AZ, TX only).” The result is that the table in

paragraph (c) now contains two overlapping entries: “Fruit, citrus group 10 (CA, AZ, TX only)” of 0.35 ppm and an entry for “Fruit, citrus group 10-10 (CA, AZ, TX only)” of 0.6 ppm. Because “Fruit, citrus group 10 (CA, AZ, TX only)” is superseded by “Fruit, citrus group 10-10 (CA, AZ, TX only),” EPA is removing “Fruit, citrus group 10 (CA, AZ, TX only)” as a housekeeping measure.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section

408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 10, 2017.

Michael Goodis,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.448:

- i. Add alphabetically the entries for “Beet, sugar, dried pulp” and “Beet, sugar, root” to the table in paragraph (a).

- ii. Revise paragraph (b).

- iii. Revise the two entries for “Alfalfa” in the table in paragraph (c);

- iv. Add alphabetically the entries for “Bermuda grass, forage (EPA Regions 9-10 only)” and “Bermuda grass, hay (EPA Regions 9-10 only)” to the table in paragraph (c); and

- v. Remove the entry for “Fruit, citrus group 10 (CA, AZ, TX only)” in the table in paragraph (c).

The additions and revisions read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* * *
Beet, sugar, dried pulp	0.30
Beet, sugar, root	0.15
* * *	* * *

(b) *Section 18 emergency exemptions.* [Reserved]

(c) * * *

Commodity	Parts per million
Alfalfa, forage (EPA Regions 7-11 only)	20
Alfalfa, hay (EPA Regions 7-11 only)	60
* * *	* * *
Bermuda grass, forage (EPA Regions 9-10 only)	40
Bermuda grass, hay (EPA Regions 9-10 only)	70
* * *	* * *

* * * *

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